EU DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE (90/385/EEC)

EU DECLARATION OF CONFORMITY

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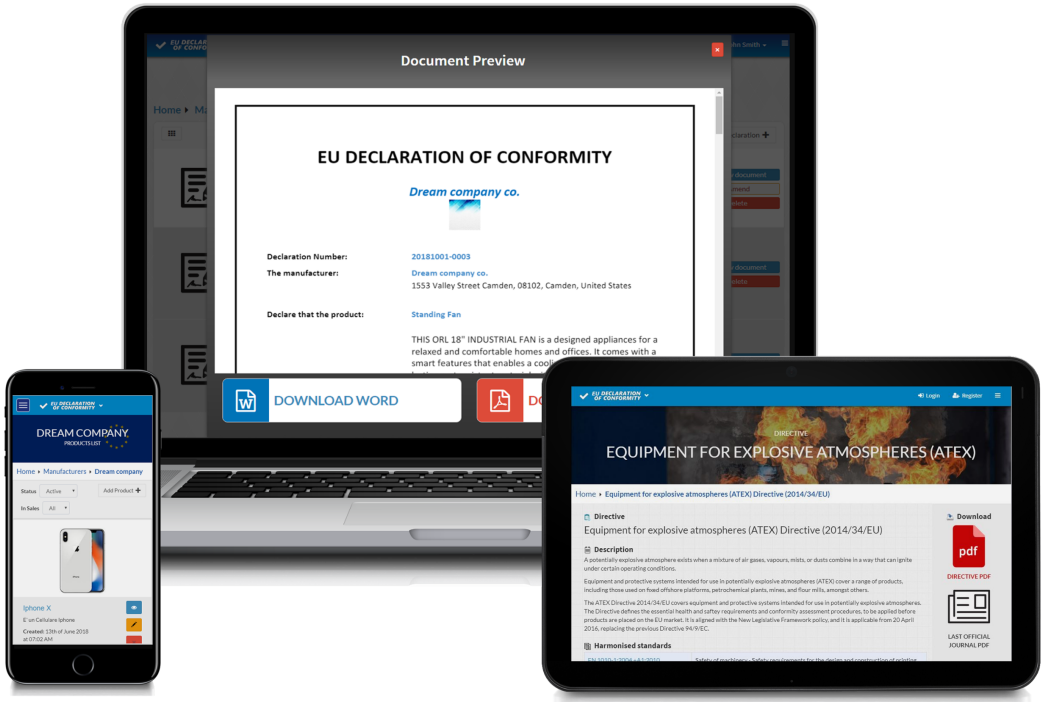

COMMISSION IMPLEMENTING DECISION (EU) 2020/438

of 24 March 2020

on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([1]), and in particular Article 10(6) thereof,

Whereas:

(1) In accordance with Article 5(1) of Council Directive 90/385/EEC ([2]) Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of active implantable medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.

(2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991 and M/295 of 9 September 1999, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 90/385/EEC.

(3) On the basis of the request M/295 of 9 September 1999, CEN revised the harmonised standard EN ISO 10993-11:2009, the reference of which has been published in the *Official Journal of the European Union* ([3]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standard EN ISO 10993-11:2018.

(4) The Commission together with CEN has assessed whether the harmonised standard EN ISO 10993-11:2018 complies with the request.

(5) The harmonised standard EN ISO 10993-11:2018 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(6) The harmonised standard EN ISO 10993-11:2018 replaces the harmonised standard EN ISO 10993-11:2009. It is therefore necessary to withdraw the reference of standard EN ISO 10993-11:2009 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in standard EN ISO 10993-11:2018, it is necessary to defer the withdrawal of the reference of standard EN ISO 10993-11:2009.

(7) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN revised the harmonised standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and EN ISO 13485:2016, the references of which have been published in the *Official Journal of the European Union* ([4]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018.

([1]) OJ L 316, 14.11.2012, p. 12.
([2]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
([3]) OJ C 389, 17.11.2017, p. 22.
([4]) OJ C 389, 17.11.2017, p. 22.

(8) The Commission together with CEN has assessed whether the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 comply with the request.

(9) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 satisfy the requirements which they aim to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the references of those standards and of the corrigendum in the *Official Journal of the European Union*.

(10) The harmonised standards EN ISO 11137-1:2015/A2:2019, EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 replace the harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 respectively. It is therefore necessary to withdraw the references of the harmonised standard EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018, it is necessary to defer the withdrawal of the references of harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016.

(11) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN drafted the new harmonised standard EN ISO 25424:2019. The Commission together with CEN has assessed whether that standard complies with the request.

(12) The harmonised standard EN ISO 25424:2019 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(13) In the interests of clarity and legal certainty, a complete list of references of harmonised standards drafted in support of Directive 90/385/EEC and satisfying the essential requirements they aim to cover should be published in one act. The other references of standards published in the Commission communication 2017/C 389/02 ([5]) should therefore also be included in this Decision. That Communication should therefore be repealed from the date of entry into force of this Decision. However, it should continue to apply in respect of the references of the harmonised standards that are withdrawn by this Decision, given that it is necessary to defer withdrawal of those references.

(14) In accordance with the second subparagraph of Article 120(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([6]), certificates issued by notified bodies in accordance with Directive 90/385/EEC from 25 May 2017 are to remain valid until the end of the period indicated on the certificate, which is not to exceed five years from its issuance. They are, however, to become void at the latest on 27 May 2024. In accordance with the first subparagraph of Article 120(3) of Regulation (EU) 2017/745 a device which has a certificate that was issued in accordance with Directive 90/385/EEC and that is valid by virtue of Article 120(2) of Regulation (EU) 2017/745, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with Directive 90/385/EEC, and provided there are no significant changes in the design and intended purpose. This Decision should therefore apply only until 26 May 2024.

(15) The requirements for implantable medical devices laid down in Directive 90/385/EEC are different from those laid down in Regulation (EU) 2017/745. The standards drafted in support of Directive 90/385/EEC should therefore not be used to demonstrate conformity with the requirements of Regulation (EU) 2017/745.

(16) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

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([5]) Commission communication in the framework of the implementation of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (2017/C 389/02) (OJ C 389, 17.11.2017, p. 22).

([6]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

Commission communication 2017/C 389/02 is repealed. It shall continue to apply until 30 September 2021 in respect of the references of the harmonised standards listed in Annex II to this Decision.

Article 3

The harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annexes I and II to this Decision may not be used to confer presumption of conformity with the requirements of Regulation (EU) 2017/745.

Article 4

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until 26 May 2024.

Done at Brussels, 24 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

No	Reference of the standard
1.	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
2.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
3.	EN 1041:2008 Information supplied by the manufacturer of medical devices
4.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010
5.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
6.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
7.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
8.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
9.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) EN ISO 10993-7:2008/AC:2009
10.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)
11.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
12.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
13.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
14.	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)
15.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)

No	Reference of the standard
16.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)
17.	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)
18.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
19.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
20.	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)
21.	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)
22.	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)
23.	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
24.	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009
25.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
26.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
27.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)
28.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)
29.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)
30.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)

No	Reference of the standard
31.	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)
32.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)
33.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
34.	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011) EN ISO 14155:2011/AC:2011
35.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
36.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
37.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
38.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
39.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)
40.	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
41.	EN 45502-2-1:2003 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
42.	EN 45502-2-2:2008 Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) EN 45502-2-2:2008/AC:2009 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
43.	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
44.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
45.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
46.	EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

ANNEX II

No	Reference of the standard
1.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
2.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
3.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)
4.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2016